FDA 510(k) Premarket Notification

K193421 Smart Alarm Interface

CLEARED

Oct 30, 2020
326 days to decision

K193421 · Product code: **MSX** · Cardiovascular
Source: https://www.510kdatabase.net/k193421/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Network And Communication, Physiological Monitors (MSX)
Date received	Dec 9, 2019
Decision date	Oct 30, 2020
Days to decision	326 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Boxview, LLC**
Location	Oklahoma City, OK, US
Contact	Cody Guest
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Steurer Consulting Group**
Contact	Robert Steurer

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov